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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,728	01/29/2004	Moises Calderon		7953

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EXAMINER	
ALEXANDER, JOHN D	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,728	CALDERON, MOISES	
	Examiner	Art Unit	
	John D. Alexander	3762	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13-17* is/are allowed.

6)☒ Claim(s) *1-5 and 18-19* is/are rejected.

7)☒ Claim(s) *6-12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utterberg (Patent No. 5360395) in view of Leschinsky et al (Patent No. 5439448).

- Regarding **Claim 1**, Utterberg discloses a section of blood flow tubing having first and second ends and an interior (Fig. 1, element 26); and first and second cannula adapters attached to the first and second ends of the tubing, respectively (Figs. 1 & 3, elements 24 & 30), each of said cannula adapters comprising: (i) a body having a passageway and first and second ends, wherein the first end of the cannula adapter body is attached to the section of tubing such that the cannula adapter passageway is in fluid communication with the interior of the tubing (Figs. 1 & 3; elements 26 & 40), and wherein the second end of said cannula adapter body is adapted for attachment to a cannula (Figs. 1 & 3; elements 22 & 32); and (ii) a vent extending through the cannula adapter body from the passageway through to an exterior of the cannula adapter body (Figs. 1 & 3; element 38), wherein the vent is sealable

for selectively opening and closing the vent (Fig. 1, elements 36 & 44). Utterberg does not explicitly disclose that the section of tubing is translucent. However, Leschinsky et al disclose blood carrying tubing that is most preferably formed of a clear material (Col. 6, lines 5-7). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Leschinsky et al to modify the blood flow tubing of Utterberg to be translucent. The motivation would have been to enable the clinician to view the interior of the tubing to detect bubbles or other contaminants (Leschinsky et al, Col. 6, lines 5-9). Regarding applicant's preamble that recites, "an atrial-arterial shunt for pump-assisted myocardial revascularization without cardiopulmonary bypass," it has not been given patentable weight because of the holding that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). Regarding applicant's recitation, "for priming purposes" on lines 14-15 of the claim, the limitation has not been given patentable weight because of the holding that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

- Regarding **Claim 2**, Utterberg further discloses a cap removably attached to the vent of each cannula adapter (Fib. 1, unnumbered ends elements 36 & 44). Regarding applicant's recitation, "for selectively opening and closing the vent for priming purposes," remarks made above regarding intended use apply here as well.

- Regarding **Claim 3**, Utterberg further discloses that the section of tubing has a length of no more than two meters (Fig. 1, element 26; Col. 4, lines 29-30). Here, Utterberg discloses that the outer diameter of the tubing is between 8.5 and 12.5 mm. It is therefore easy to infer, from comparison of the diameter and length of element (26) in Fig. 1, that the length of the tubing is not more than 2m. Regarding applicant's recitation, "to reduce the amount of blood required to fill the shunt for use in pump-assisted myocardial revascularization," remarks made above regarding intended use apply here as well.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utterberg in view of Leschinsky et al as applied to Claims 1-3 above, and further in view of Rawles et al (Patent No. 6890316).

- Regarding **Claim 4**, Utterberg discloses that his blood flow tubing is easily rolled and packaged (Fig. 2; Col. 2, lines 51-53), but neither Utterberg nor Leschinsky discloses packaging in a sealed, openable container having a sterile interior. Regarding all other elements of the claim, comments made above in rejection of Claim 1 apply here as well. Rawles et al disclose a tubing set for a blood handling system that includes placing the tubing in a sealed, openable container having a sterile interior (Fig. 5, elements 60 & 65). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Rawles et al to modify the packaging of Utterberg to include such a sealed, openable container with a sterile interior. The motivation would have been to prevent contamination of the tubing, and possible subsequent contamination of the patient's blood, while handling it before connection to the cannulae.
- Regarding **Claim 5**, comments made above in rejection of Claim 2 apply here as well.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orejola (Patent No. 4985014) in view of Leschinsky et al.

- Regarding **Claim 18**, Orejola discloses a method of pump-assisted myocardial revascularization without cardiopulmonary bypass comprising the steps of: surgically attaching a first cannula to a first location on a patient's heart (Fig. 3, elements 36 & 38); surgically attaching a second cannula to a second location on the patient's heart (Fig. 3, elements 44 & 46); interconnecting the first and second cannulae with a sterile atrial-arterial shunt (Fig. 3, element 22), the shunt comprising a section of tubing terminated at a first end by a first cannula adapter and at a second end by a second cannula adapter and the first and second cannula adapters are respectively connected to the first and second cannulae (Fig. 3, elements 12 & 14; Fig. 5, elements 32 & 40); inserting the shunt tubing into a peristaltic pump (Fig. 3, elements 10, 24, 26, & 28); and activating the peristaltic pump to pump blood through the shunt; wherein the first and second locations on the patient's heart are chosen so that when the peristaltic pump is activated it acts to operably pump blood in parallel to the pumping action of the patient's heart (Col. 1, lines 5-12 & 48-68). Orejola does not explicitly disclose a step of priming the shunt to remove air or that each cannula adapter has a vent, said vent being sealable for selectively opening and closing the vent for priming purposes. However, Leschinsky et al disclose a method and apparatus for connecting blood carrying tubing that include such a priming step and sealable, vented cannula adapter structures (Figs. 8, 9, & 10, elements 110, 116, 128, & 130; Col. 9, lines 16-57). Leschinsky et al also teach that the connection method and apparatus can be used to connect a blood carrying cannula to another blood carrying tube or to an external pump (Col. 1, lines 31-35). It would have been

obvious to one of ordinary skill in the art at the time of applicant's invention from the teachings by Leschinsky et al to modify the cannula adapters of Orejola to include a sealable vent for priming purposes. The motivation would have come from Leschinsky et al's teaching that great care must be taken when connecting blood carrying cannulae such as those of Orejola in order to prevent introduction of air or other contaminants that can be harmful or fatal to a patient (Col. 1, lines 35-39). Further motivation would have come from Leschinsky et al's teaching that sealable, vented cannula adapters allow for air bubbles to be easily removed during a priming step (Col. 7, lines 39-55). If Leschinsky et al and Orejola are combined, Orejola's element (30) of Fig. 5 would be analogous to Leschinsky et al's connector (120) of Fig. 8, and each of Orejola's cannulae (32) and (40) would be analogous to Leschinsky et al's second tube (112). Regarding the limitation that the section of tubing is translucent, comments made above in rejection of Claim 1 apply here as well. Regarding applicant's recitation, "the peristaltic pump is one of a medical facility's existing peristaltic pumps from a cardiopulmonary bypass machine," examiner considers that Orejola's pump is obviously a medical facility's existing pump and that, under a broadest reasonable interpretation, it is part of a cardiopulmonary bypass machine because it provides an accessory pathway of cardiac output from the ventricles to the aorta and/or pulmonary artery.

- Regarding **Claim 19**, Orejola further discloses that the section of tubing has a length of no more than two meters. Here, Orejola discloses that the inside diameter of tubing (32) is 5/16 inch. It is therefore easy to infer, from comparison of the diameter of tubing (32) and the length of tubing (22) in Fig. 3, that the length of tubing (22) is not more than 2m. Orejola

further discloses the method of moving the peristaltic pump close to the patient (Col. 1, lines 54-56).

Allowable Subject Matter

Claims 6-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding Claims 6 and 7, the prior art of record does not disclose or suggest a system with the elements of Claim 4 and further including a peristaltic pump from a medical facility's cardiopulmonary bypass machine. Regarding Claims 8-12, the prior art of record does not disclose or suggest a system with the elements of Claim 4 and further including a second sterile atrial-arterial shunt sealed in the container and generally identical to the first shunt.

Claims 13-17 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not disclose or suggest a method of pump-assisted myocardial revascularization without cardiopulmonary bypass that includes surgically attaching first and second cannulae to the aorta and left atrium respectively, interconnecting the first and second cannulae with tubing having vented cannula adapters, and inserting the tubing into a peristaltic pump from a medical facility's cardiopulmonary bypass machine.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Carlsson et al (Patent No. 4629448) disclose a tube set for extracorporeal treatment of blood that includes vented cannula adapters.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA

KENNEDY SCHAETZLE
PRIMARY EXAMINER
9-2-05